SULLIVAN & WORCESTER

Sullivan & Worcester LLP
1633 Broadway
New York, NY 10019

T 212 660 3000
F 212 660 3001
www.sandw.com

September 16, 2013

By ECF and Federal Express

Hon. Shira A. Scheindlin
United States District Court
Southern District of New York
500 Pearl St., Room 1620
New York, NY 10007

Re: *Sekisui America Corporation v. Hart*, 12 CV 3479 (SAS) (FM)

Dear Judge Scheindlin:

We represent Richard Hart and Marie Louise Trudel-Hart (the "Harts") in the above-referenced action. We write this letter pursuant to Rule IV(A) of this Court's individual rules and pursuant to this Court's order issued at the pre-trial conference on August 26, 2013 that each party submit a double-spaced letter no longer than 10 pages setting forth the grounds for each parties' intended motions *in limine*.

I. All Plaintiffs' Claims Are Time-Barred Other Than Those Identified In The Claim Notice.

Pursuant to Section 9.1 (Survival) of the Stock Purchase Agreement (the "SPA"), Plaintiffs' claims for breaches of representations and warranties are barred except those expressly set forth in a Claim Notice on or before October 20, 2010, *i.e.*, eighteen months after April 20, 2009 (the "Closing Date"). *See* SPA § 9.1, attached hereto as Exhibit ("Exh.") 1.[1] In their Claim Notice, dated October 14, 2010, Plaintiffs asserted that the Harts breached a number of representations and warranties relating to FDA compliance: SPA §§ 4.12 (compliance of buildings and facilities in material respects with all applicable laws), 4.14(a) (compliance of company in material respects with all applicable laws), 4.14(c) (possession of relevant product permits and records) and 4.14(d) (compliance with FDA regulations). In their Complaint, filed on May 2, 2012, nineteen months after they sent the Claim Notice, Plaintiffs reiterated their claims for breaches of §§ 4.12, 4.14(a), 4.14(c) and 4.14(d), but for the first time asserted claims for breaches of §§ 4.11

[1] Exhibits include only the relevant pages of the documents cited.

(Product Warranty), 4.14(f) (no false statements to the FDA) and 4.26 (Key Customers). Plaintiffs' damages expert, Guy F. Erb, stated in his report dated July 3, 2013, that the "alleged breached representations and warranties" included §§ 4.6 (Financial Statements), 4.7 (No Undisclosed Liabilities), 4.8 (Absence of Certain Changes or Events) and 4.28 (Completeness of Disclosure) of the SPA. *See* Expert Report of Guy F. Erb, July 3, 2013, attached hereto as Exh. 2, ¶¶ 47(a)-(k).

All of Plaintiffs' claims for breaches of representations and warranties (whether alleged in the Complaint or otherwise asserted by Plaintiffs in their expert reports) are time-barred except those set forth in the Claim Notice, *i.e.*, §§ 4.12, 4.14(a), 4.14(c) and 4.14(d) of the SPA (relating to FDA compliance).[2] Section 9.1, captioned "Survival," provides in relevant part: "the representations and warranties of the parties hereto contained in this Agreement … will survive in full force and effect until the date that is 18 months after the Closing Date." SPA § 9.1. It further provides: "any representation or warranty that would otherwise terminate in accordance with the immediately proceeding sentence will continue to survive if a Claim Notice shall have been timely given under this Article IX on or prior to such termination date … until the matters described in the Claim Notice have been satisfied or otherwise resolved … but only with respect to matters described in the Claim Notice." *Id.*

New York law enforces such survival clauses. *See* N.Y. C.P.L.R. § 201; *Carmeuse v. M.J. Satvola Indus., Inc.*, 823 F. Supp. 125, 131 (S.D.N.Y. 1993); *Dimmick v. N.Y. Prop. Underwriting Ass'n*, 57 A.D.3d 602, 602 (2d Dep't 2008); *In re Village of Saltaire v. Zagata*, 280 A.D.2d 547, 547-48 (2d Dep't 2001); *Hurlbut v. Christiano*, 63 A.D.2d 1116, 1117 (4th Dep't 1978). The language of the SPA indicates that the parties' intent was not only to establish that a right to assert a claim expires but also to shorten the statute of limitations for certain claims. Plaintiffs' claims for breaches of §§ 4.6, 4.7, 4.8, 4.11, 4.14(f), 4.26 and 4.28 are time-barred as they were

[2] Under § 9.1, Plaintiffs' claim for breach of § 4.14(f) is not time-barred. However, Plaintiffs have not alleged that the Harts made any false statements to the FDA, rendering Plaintiffs' claim for breach of § 4.14(f) moot.

not in the Claim Notice but were raised for the first time in their Complaint or expert reports after the provisions expired on October 20, 2010.[3]

II. Plaintiffs' Experts' Testimony Should Be Excluded.

A. The Testimony of Guy F. Erb Should Be Excluded In Its Entirety.

Mr. Erb's report opines on damages for claims which are time-barred, calculates damages based on projections specifically disclaimed in the SPA, calculates damages using an unrecognized methodology, asserts a violation of a Material Adverse Change ("MAC") clause in contravention of New York law, and calculates certain damages for which no expert is needed.

1. Mr. Erb Improperly Calculates Damages for Claims Which Are Time-Barred.

In his report, Mr. Erb calculates damages totaling approximately $10.7 million for alleged breaches of §§ 4.6, 4.7, 4.8, 4.11, 4.14(f), 4.26 and 4.28 of the SPA. As set forth in Section I, *supra*, claims alleging breach of these sections are time-barred.[4]

2. Mr. Erb Improperly Relies on Projections In The Confidential Memorandum.

For the alleged breaches of §§ 4.6, 4.7, 4.8, 4.11, 4.14(f), 4.26 and 4.28 of the SPA, Mr. Erb calculates Plaintiffs' damages as the difference between the projections in the Confidential Memorandum and the "actual sales performance of the ADI product slate and Femtelle for the four years and 2 1/3 months after the closing[.]" Exh. 2 ¶ 69. Mr. Erb's reliance on the projections on the Confidential Memorandum is improper.[5] As this Court noted in its decision and

[3] There are no representations and warranties at issue in the litigation other than as set forth in this letter. Plaintiffs have asserted no claims based on any other representations and warranties, and Plaintiffs' damages expert does not opine that his damages calculation is based on breaches of any other representations and warranties. *See* Exh. 2 ¶¶ 47(a)-(k).

[4] In its decision and order dated October 17, 2012, this Court stated that § 4.28 may be the relevant provision for a claim for breach of contract related to FEMTELLE. Section 4.28 provides that all representations and warranties in the SPA are true and accurate. While the Harts contend there are no representations and warranties regarding FEMTELLE (and Plaintiffs have not cited any), to the extent Plaintiffs rely on § 4.28 to support their FEMTELLE claim, the claim is time-barred.

[5] Mr. Erb claims that he based his calculations on KPMG's post-acquisition Purchase Price Allocation ("PPA"). *See* Transcript of Deposition Guy F. Erb, Aug. 28, 2013, attached hereto as Exh. 3, at 22:25; 23:7-11. As Mr. Erb concedes, however, KPMG used the projections in the

order dismissing the fraud claims, the SPA contains a disclaimer that "renders Sekisui's reliance upon the Confidential Memorandum unreasonable[.]" Dkt. 28, p. 18. Mr. Erb concedes that the Harts made no representation or warranty regarding the projections in the Confidential Memorandum. *See* Exh. 3 at 78:11-15. Accordingly, Mr. Erb cannot base his damages calculations on the projections in the Confidential Memorandum.

3. Mr. Erb's "Reliance" Methodology to Calculate Damages is Improper.

Mr. Erb estimates Plaintiffs' damages for breach of the representations and warranties using a reliance approach, *i.e.*, the difference between what was represented as value and what later turned out to be true value. Exh. 2 ¶ 17. For support, Mr. Erb cites "Reference Guide on Estimation of Economic Losses in Damages Awards." *Id.* (*citing* Robert E. Hall & Victoria A. Lazear, "Reference Guide on Estimation of Economic Losses In Damages Awards," in Reference Manual on Scientific Evidence (2d ed. 2004), p. 284, attached hereto as Exh. 4). According to Hall & Lazear, however, damages for breaches of contract "are generally calculated under the expectation principle, where the compensation is intended to replace what the plaintiff would have received if the promise or bargain had been fulfilled." Exh. 4, p. 283; *see also Trinity Biotech, Inc. v. Reidy*, 665 F. Supp. 2d 377, 382 (S.D.N.Y. 2009). Hall & Lazear make plain that reliance damages are appropriate, instead, for claims of fraud. *See* Exh. 4, p. 283.

Rather than starting with Plaintiffs' expectation—their valuation of ADI at the time of purchase, for which they retained GCA Savvian—Mr. Erb starts with the projections in the Confidential Memorandum and then calculates Plaintiffs' damages as the difference between those projections and the "actual sales performance of the ADI product slate and Femtelle for the four years and 2 1/3 months after the closing[.]" Exh. 2 ¶ 69. This methodology does not comport with New York law. *See Aroneck v. Atkin*, 90 A.D.2d 966, 967 (4th Dep't 1982) (breach of contract damages are based on "what knowledgeable investors anticipated the future conditions and performance would be" at time of alleged breach, not on "the actual economic conditions and

---

Confidential Memorandum for the PPA. *Id.* at 23:1-3. KPMG was no more entitled to rely on the Confidential Memorandum than was Mr. Erb.

performance" years after the sale); *see also Lucente v. IBM*, 310 F.3d 243, 262 (2d Cir. 2002); *Sharma v. Skaarup Ship Mgmt. Corp.*, 916 F.2d 820, 825 (2d Cir. 1990).

4. A Short-Term Decline In EBITDA Does Not Constitute A Material Adverse Effect.

Mr. Erb opines that ADI's trailing twelve-month earnings before interest, tax, depreciation and amortization ("TTM EBITDA") declined by 33 percent between December 31, 2008 and the end of February 2009. Exh. 2 ¶ 44. Section 4.8 of the SPA provides that, "since June 30, 2008, the Business has been conducted in the Ordinary Course of Business and there has not been any change, event, state of circumstances or facts, or occurrence that … has had or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect[.]" SPA § 4.8. Mr. Erb cites § 4.8 on page 13 of his report, and he opines that "the decline in sales of Then-Current Products can be largely explained by the breaches, for example, the undisclosed deterioration in ADI's financial performance in early 2009[.]" Exh. 2 ¶ 80. As shown above, such a claim is time-barred. It is also prohibited by New York law.

A decline in TTM EBITDA does not constitute a material adverse effect. *See In re IBP, Inc. Shareholders Litig.*, 789 A.2d 14, 68 (Del. Ch. 2001) (interpreting NY law) ("[a] short term hiccup in earnings should not suffice; rather the Material Adverse Effect should be material when viewed from the longer-term perspective of a reasonable acquirer"). During his deposition, Mr. Erb admitted that his analysis was of short-term earnings only. Transcript of Deposition Guy F. Erb, Aug. 28, 2013, attached hereto as Exh. 3, at 103:10-12 ("you'd want to look at more than just one quarter to make any assessment" of what TTM EBITDA signaled about a company's long-term health). Mr. Erb's reliance on a short-term decline in ADI's TTM EBITDA to establish breach of the MAC clause and resulting damages renders his opinion unreliable and, thus, inadmissible. *See Alfa Corp. v. OAO Alfa Bank*, 475 F. Supp. 2d 357, 360 (S.D.N.Y. 2007).

5. Mr. Erb's Opinion Regarding Remediation Is Not Proper Expert Testimony.

Mr. Erb also concludes that Plaintiffs are entitled to $2.984 million in damages for remediation expenses related to breached representations and warranties regarding FDA

compliance (*i.e.,* the representations and warranties identified in the Claim Notice). *See* Exh. 2 at Exhibit 1 (no page number). As Mr. Erb admitted at his deposition, this calculation does not require any expertise, only arithmetic and checking documents. Exh. 3 at 113:23-114:3. Mr. Erb conceded that the calculations could have been done by an accounting firm. Exh. 3 at 114:15-17. The arithmetic and document review done by Mr. Erb are "lay matters which [the trier of fact] is capable of understanding and deciding without expert help." *Liberty Media Corp. v. Vivendi Universal, S.A.*, 874 F. Supp. 2d 169, 172 (S.D.N.Y. 2012).

B. The Testimony of Timothy A. Ulatowski Should Be Excluded In Its Entirety.

Plaintiffs proffer Timothy Ulatowski to opine that a regulatory submission seeking approval of an ADI product called FEMTELLE (the "FEMTELLE 510(k)"), was destined to fail and that ADI's decision to withdraw the FEMTELLE 510(k) in June 2010 was the right decision. *See* Expert Report of Timothy A. Ulatowski, July 3, 2013, attached hereto as Exh. 5, pp. 24, 31. Although not stated, Mr. Ulatowski's report appears to respond to the Hart's counterclaim that Plaintiffs breached SPA § 2.6(d)(i), which required Plaintiffs to "undertake commercially reasonable efforts to market and sell, or to cause the marketing and sale of, the FEMTELLE Product …" and "not willfully take any actions, or omit to take any actions, with the intent of preventing the Business from meeting FEMTELLE Revenue targets set forth on Exhibit A …." SPA § 2.6(d)(i)(A-B). The issue with respect to the Harts' claims is Plaintiffs' state of mind at the time they withdrew the 2009 510(k), and their decision not to file a new 510(k). Testimony by Mr. Ulatowski regarding "the intent, motives or states of mind of corporations, regulatory agencies and others [has] no basis in any relevant body of knowledge or expertise." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004).

In addition, Mr. Ulatowski's conclusion that the 2009 510(k) was "destined to fail" is a legal conclusion that is not permissible expert testimony. *See Liberty Media Corp.*, 874 F. Supp. 2d at 172.

Finally, the bulk of the "Opinions" section of Mr. Ulatowski's report is a narrative of the facts. *See* Exh. 5, pp. 18-28; 30; 32; 34 (recounting facts and describing documents reviewed).

This is not proper expert testimony. *See Liberty Media Corp.*, 874 F. Supp. 2d at 172 (expert witness may not "merely repeat[] facts or opinions stated by other potential witnesses or in documents produced in discovery"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (expert precluded from "testifying as to the knowledge, motivations, intent, state of mind, or purposes of [the company], its employees, the FDA, or FDA officials").

C. The Testimony of Carrie M. Kuehn Should Be Excluded In Its Entirety.

Plaintiffs proffer Carrie M. Kuehn as their FDA compliance expert. The core of Ms. Kuehn's opinion is that "ADI was not in compliance with all applicable laws and regulations between 2006 and 2009 as warranted in the SPA." Expert Report of Carrie M. Kuehn, July 3, 2013, attached hereto as Exh. 6, p. 39 ("Summary"). This is plainly an "ultimate legal conclusion[]" and, as such, is impermissible. *Liberty Media*, 874 F. Supp. 2d at 172.

Ms. Kuehn's other opinions comprise a description of the documents she reviewed and a series of conclusions that ADI was not in compliance with FDA regulations. Ms. Kuehn does not explain how the documents she reviewed demonstrate ADI's non-compliance. *See, e.g.*, Exh. 6, p. 12. For example, Ms. Kuehn opines that lack of written job descriptions is "a clear violation of the QSRs,[6] which require that employees be fully trained and have 'the necessary education, background, training, and experience to assure that all activities required by [21 CFR 820.25] are correctly performed.' Without proper personnel regulations, ensuring compliance with this regulation would have been nearly impossible." *Id.* The QSRs nowhere require written job descriptions, and Ms. Kuehn offers no basis for her conclusions that they do. Nor does she provide a basis for her conclusion that a failure to maintain written job descriptions constitutes a lack of "proper personnel regulations." *Id.*

Ms. Kuehn never "explain[s] the regulatory context in which [the documents] were [or should have been] created, defin[es] any complex or specialized terminology, or draw[s] inferences that would not be apparent without the benefit of experience or specialized

[6] Quality System Regulations.

knowledge." *In re Fosamax*, 645 F. Supp. 2d at 192. Her opinions "are too conclusory [and] insufficiently based on expertise or analysis to be admitted." *Id.; see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) ("nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"); *see also* Fed. R. Civ. P. 26(a)(2)(B)(i).

Ms. Kuehn also fails to offer any testimony regarding "the complex regulatory framework that informs the standard of care for the" medical device manufacturing industry. *In re Fosamax*, 645 F. Supp. 2d at 191. Her references to FDA regulations are limited to quoting or paraphrasing the regulations. *See., e.g.*, Exh. 6, p. 13 ("The QSRs require medical device companies to perform internal audits of their QMS on a regular schedule."); Exh. 6, p. 15 ("Design control activities should be clearly described and implemented in the form of standard operating procedures (SOPs) under the company's QMS, and should be subject to continuous improvement under scheduled management reviews of the QMS."); Exh. 6, p. 19 ("Manufacturers are required to establish, implement, and maintain document control procedures that define activities related to document approval, distribution, and change control."). Although her references to FDA regulations contain terms of art, Ms. Kuehn neither defines nor explains these terms.

III. The Court's Ruling Regarding Spoliation of Evidence Should Be Extended.

On August 15, 2013, this Court held that the Harts are entitled to an adverse inference instruction at trial due to Plaintiffs' willful destruction of the email folders of Richard Hart and Leigh Ayres. *See* Dkt. 52. The Harts have uncovered still more spoliation. Plaintiffs destroyed information on servers that contained ADI's FDA compliance files, and also destroyed backup tapes.[7] With respect to this spoliation, the Harts can state what was lost and show its importance. The backup data that was erased contained documents demonstrating that ADI was

[7] As of October 15, 2009, Sekisui had ADI's "entire data," including pre-acquisition data, backed up on tapes. *See* Email from Dicey Taylor to Leigh Ayres, dated October 15, 2009 (SEK00985278), attached hereto as Exh. 7. Plaintiffs have conceded the loss of this evidence and that there are no tapes now available. *See* Transcript of Hearing before Magistrate Judge Maas, April 8, 2013, at 4:12, attached hereto as Exh. 8.

FDA compliant, *i.e.*, ADI's standard operating procedures ("SOPs"), as well as other compliance documents. Indeed, it is the absence of these documents which underlies Plaintiffs' expert report. This Court should extend the adverse inference to apply to the documents that were on the servers and backup tapes.

Plaintiffs' FDA expert, Carrie M. Kuehn, opined that ADI was not in compliance with FDA regulations during the relevant period because ADI did not have, *inter alia*, final SOPs required by the regulations. *See, e.g.*, Exh. 6, pp. 19-23. A document from April 2006, however, shows that at least 200 approved (*i.e.*, final) SOPs and associated forms were stored on ADI's shared drive. *See* Procedure, Change Review, dated April 20, 2006 (SEK00110912-14), attached hereto as Exh. 10. Ms. Kuehn specifically opined that ADI did not have final versions of the SOP for Operation and Maintenance of the Powers Scientific, Inc. -20°C Freezer (EQP011) and two associated forms (EQP011-1F and EQP011-2F); the SOP for Operation and Maintenance of the Koagulab M Coagulation System (EQP025) and an associated form (EQP025-1F); the SOP for Operation and Maintenance of the Oyster Bay Plate Processor (EQP036); and the SOP for Operation and Maintenance of the Virtis Benchmark 2000 Freeze Dryer Control System (EQP042) and an associated form (EQP042-1F). These SOPs and forms appear in the image of the file directory in Exhibit 10. *See* Exh. 10 at SEK00110913-14. In short, these documents **once existed**.[8] Ms. Kuehn's reliance on the absence of these documents to opine that ADI was not in regulatory compliance establishes that the lost documents are favorable to the Harts' defense.

Finally, as the Court will recall, after claiming for several months that no such ESI existed, at the pre-trial conference on August 26, 2013, Plaintiffs' counsel promised to deliver the ESI of Michael Smirnov and Janet Silbert. This production arrived on Friday, September 13 at 2:18 p.m., the start of Erev Yom Kippur, and the last work day before the deadline to submit this letter to the Court. Plaintiffs' woefully delinquent production was made six months after it was due,

[8] It appears that the data was lost in January 2011, when Plaintiffs upgraded their servers. *See* Memo from Doug LeMasurier to ADI, dated February 16, 2011 (SEK00972868-70), attached hereto as Exh. 11. Even had these files been backed up, Plaintiffs conceded that "[t]here [are] no back-up tapes" and their IT vendor could not recover any ESI. Exh. 8, 4:12-13.

more than two months after the close of fact discovery, and two weeks after the close of expert discovery. It consisted of a mere 2,765 files (many of which are duplicates or images of the company's logo). It contained 169 emails for Michael Smirnov, none of which were sent or received during the relevant period. It contained 18 emails for Janet Silbert during the relevant period, only **one** of which was sent by Ms. Silbert between February 20 and April 20, 2009, the period during which Plaintiffs allege they did not receive critical financial information.

This conduct warrants sanctions. *See Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 436 (S.D.N.Y. 2004) (in context of allegation of spoliation, failure to timely produce documents warrants inference that destroyed evidence was relevant); *see also Residential Funding Corp. v. DeGeorge Fin. Corp.*, 306 F.3d 99, 112 (2d Cir. 2002) ("discovery conduct that might have been considered 'merely' discourteous at an earlier point in the litigation may well breach a party's duties to its opponent and to the court").

Respectfully submitted,

/s/

Franklin B. Velie

Direct line: (212) 660-3037
fvelie@sandw.com

cc: Karen L. Hagberg, Esq.
Craig B. Whitney, Esq.
Natalie A. Fleming Nolen, Esq.

Pursuant to the parties' Confidentiality Stipulation, Exhibits 1 through 11 are designated "Confidential." They are not being filed publicly. Hard copies are being sent to the Court.